

THE INSURANCE CODE OF 1956 (EXCERPT)
Act 218 of 1956

500.3406q Off-label use of approved drug; coverage; conditions; compliance; use of copayment, deductible, sanction, or utilization control; limitation; definitions.

Sec. 3406q. (1) An expense-incurred hospital, medical, or surgical policy or certificate delivered, issued for delivery, or renewed in this state that provides pharmaceutical coverage and a health maintenance organization contract that provides pharmaceutical coverage shall provide coverage for an off-label use of a federal food and drug administration approved drug and the reasonable cost of supplies medically necessary to administer the drug.

(2) Coverage for a drug under subsection (1) applies if all of the following conditions are met:

(a) The drug is approved by the federal food and drug administration.

(b) The drug is prescribed by an allopathic or osteopathic physician for the treatment of either of the following:

(i) A life-threatening condition so long as the drug is medically necessary to treat that condition and the drug is on the plan formulary or accessible through the health plan's formulary procedures.

(ii) A chronic and seriously debilitating condition so long as the drug is medically necessary to treat that condition and the drug is on the plan formulary or accessible through the health plan's formulary procedures.

(c) The drug has been recognized for treatment for the condition for which it is prescribed by 1 of the following:

(i) The American medical association drug evaluations.

(ii) The American hospital formulary service drug information.

(iii) The United States pharmacopoeia dispensing information, volume 1, "drug information for the health care professional".

(iv) Two articles from major peer-reviewed medical journals that present data supporting the proposed off-label use or uses as generally safe and effective unless there is clear and convincing contradictory evidence presented in a major peer-reviewed medical journal.

(3) Upon request, the prescribing allopathic or osteopathic physician shall supply to the insurer or health maintenance organization documentation supporting compliance with subsection (2).

(4) This section does not prohibit the use of a copayment, deductible, sanction, or a mechanism for appropriately controlling the utilization of a drug that is prescribed for a use different from the use for which the drug has been approved by the food and drug administration. This may include prior approval or a drug utilization review program. Any copayment, deductible, sanction, prior approval, drug utilization review program, or mechanism described in this subsection shall not be more restrictive than for prescription coverage generally.

(5) As used in this section:

(a) "Chronic and seriously debilitating" means a disease or condition that requires ongoing treatment to maintain remission or prevent deterioration and that causes significant long-term morbidity.

(b) "Life-threatening" means a disease or condition where the likelihood of death is high unless the course of the disease is interrupted or that has a potentially fatal outcome where the end point of clinical intervention is survival.

(c) "Off-label" means the use of a drug for clinical indications other than those stated in the labeling approved by the federal food and drug administration.

History: Add. 2002, Act 538, Eff. Jan. 22, 2003;—Am. 2003, Act 88, Eff. Jan. 23, 2004.

Popular name: Act 218